USDA

August 26, 2002

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics
Suite 104
510 South 17th Street
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-18

Subject: Issuance of a Conditional License for Avian Pneumovirus Vaccine, Modified Live Virus

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Biomune Company, Establishment No. 368, Lenexa, Kansas, for an Avian Pneumovirus Vaccine, Modified Live Virus.

A veterinary biological product regulated under the Virus-Serum-Toxin Act must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. The regulations in 9 CFR Part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstance. There is no other licensed vaccine currently available to aid in the prevention of disease due to avian pneumovirus in turkeys which is currently causing significant losses to producers in the upper Midwest region of the United States.

This conditional license was issued following acceptance of data supporting purity, field safety, and efficacy of the product. Distribution and use of this product is restricted to the limited area of "the State of Minnesota and adjacent States". The license will expire in one year. In accordance with 9 CFR Part 102, progress toward regular licensure must be pursued for reissuance of the conditional license.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics